Claims 1-6, 9, 11-17 and 20 were rejected under 35 U.S.C. §102(e) as being anticipated by Geistlich et al. U.S. Patent No. 6,221,109 in light of Geistlich et al. U.S. Patent No. 5,573,771. Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

The Geistlich et al. '109 patent is directed to use of collagen membranes to protect the spine after vertebral surgery. This is on an astronomically larger scale than the present invention, and is totally unrelated to the present invention.

As set forth in the present application, the nerve regeneration tubes of the present invention are for reconnecting tiny nerves by inserting nerve ends in opposite ends of the inventive regeneration tubes. In order to clarify this manifest difference, claims 1 and 13 are being amended to specify that the nerve regeneration tube has an inner diameter of about 0.5-5mm.

The distinction between the presently claimed invention and the Geistlich et al. '109 patent further is made manifestly clear by the amendments to claims 1 and 13, specifying that the nerve regeneration tube is for reconnecting nerve ends, and further specifying that the nerve regeneration tube has opposite ends into which ends of nerves are inserted for reconnection and regeneration of the nerves.

As noted above, the Geistlich et al. '109 patent utilizes a collagen membrane to protect a patients spine following vertebral surgery.

There is no hint or even remote suggestion in the Geistlich et al. '109 patent of a nerve regeneration tube for reconnecting nerve ends, the tube having opposite ends into which ends of nerves are inserted for reconnection and regeneration of the nerves, with the tube having an inner diameter of about 0.5-5mm.

The second-cited Geistlich '771 patent discloses medicinal bone mineral products, but fails to supply any of the above-noted deficiencies of the Geistlich et al. '109 patent.

In view of the above amendments and remarks, withdrawal of the rejection under 35 U.S.C. §102(e) based on Geistlich et al. '109 in light of Geistlich et al. '771 is respectfully requested.

Claims 1, 2, 5-7, 9-11 and 13 were rejected under 35 U.S.C. §102(e) as anticipated by Shimizu U.S. Patent No. 6,090,117 (hereinafter "Shimizu"). Claims 1, 5 and 7-8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Shimizu and further in view of Tonge et al. Claims 1 and 11-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shimizu and further in view of

Geistlich et al. '278. Claims 1, 15-17 and 19-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shimizu and further in view of Stensaas et al. Insofar as these rejections could apply to the claims, as amended, they are respectfully traversed.

Page 4 of the Office Action, paragraph 3, indicates that Shimizu discloses a pure collagen sidewall without use of any non-collagen materials at column 6, line 48 to column 7, line 50. However, a careful reading of this passage in the Shimizu patent will reveal that in every case, separate collagen membranes 22 and 23 are additionally formed on the inner and outer surfaces of the compressed, fine fibrous collagen layer 21. Thus, the Shimizu tube always is formed of at least three sheets.

Accordingly, the Shimizu reference fails to disclose or suggest a nerve regeneration tube "formed of a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material".

Moreover, the Shimizu reference fails to provide any suggestion whatsoever of a nerve regeneration tube formed of a single sheet, wherein the single sheet has both a compact smooth outer barrier surface and a fibrous inner surface. Absent any teaching or suggestion whatsoever of a single sheet having these properties, and forming a nerve regeneration tube, the rejection based on Shimizu should be withdrawn.

None of the other applied references can be combined with the Shimizu reference to supply the deficiencies thereof.

Tonge et al. teaches a tube filling material, but cannot be combined with Shimizu to suggest a tube formed of a single sheet of resorbable sidewall material as specifically defined above.

The Geistlich et al. '278 patent discloses a collagen material which arguably, without admitting same, could be combined with Shimizu to provide the inner and outer collagen sheets surrounding the central tube 21 of Shimizu. However, this would not teach or suggest the nerve regeneration tube formed of a single sheet of resorbable sidewall material as specifically defined above.

The Stensaas et al. reference discloses a prosthesis for nerve regeneration which is made of a fluid-impermeable layer composed of silicone, rubber, polyurethane, teflon or nitrocellulose. The Stensaas et al. reference thus cannot be combined with the Shimizu reference to suggest the invention as presently claimed.

In view of the above amendments and remarks, withdrawal of the rejections based on Shimizu, either alone or combined with Tonge et al., Geistlich et al. or Stensaas et al., is respectfully requested.

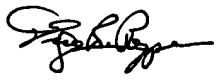
Claim 18 was objected to as being dependent on a rejected base claim. Claim 18 has been made independent, and is now believed to be allowable.

Applicants wish to make of record the accompanying references cited on accompanying Form PTO-1449, which were cited in a corresponding French search report. The relevance of the non-English-language WO99/63908 reference is set forth in the English-language EPO publication number 1 084 686. Applicants submit that none of the accompanying references derogate from patentability of the presently amended claims.

I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in the enclosed search report from a foreign patent office not more than three months prior to the filing of this statement.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,



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Attachments: Marked-Up Copy of Amendments
PTO 1449 and 4 References

Amended Claim: Version with markings to show changes made

1. (Twice Amended) A nerve regeneration tube for reconnecting nerve ends, the tube formed of a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sheet material further having a fibrous inner surface opposite the smooth barrier surface, said tube having an inner diameter of about 0.5-5mm, said tube having opposite ends into which ends of nerves are inserted for reconnection and regeneration of said nerves.

13. (Twice Amended) A nerve regeneration tube for reconnecting nerve ends, the tube formed of a single sheet of a resorbable sidewall material comprising collagen material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sidewall of the tube further having a fibrous inner surface opposite the smooth barrier surface, said tube having an inner diameter of about 0.5-5mm, said tube having opposite ends into which ends of nerves are inserted for reconnection and regeneration of said nerves.

18. (Twice Amended) A method of producing a nerve regeneration tube [as claimed in claim 1], comprising:

a) providing a sheet of collagen material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, and a fibrous surface opposite the smooth barrier surface; and

b) forming said sheet into a tube having a sidewall with said compact, smooth outer barrier surface oriented outwardly, said sidewall having an inner surface comprised of said fibrous surface opposite said smooth barrier surface;

wherein said sheet of collagen material has two opposite side edges, and the two side edges of said sheet are brought together to form said tube from said sheet;

further including a step of joining said two side edges together to form said tube from said sheet; wherein the two side edges are joined together by sutures or adhesive.